

# Behind the Invisible Curtain at the U.S. EPA Clean Air Scientific Advisory Committee (CASAC): What CASAC Does and How

Speaker:

H. Christopher Frey, North Carolina State University

Moderator:

Holly S. Stallworth, U.S. Environmental Protection Agency



AIR & WASTE MANAGEMENT  
ASSOCIATION

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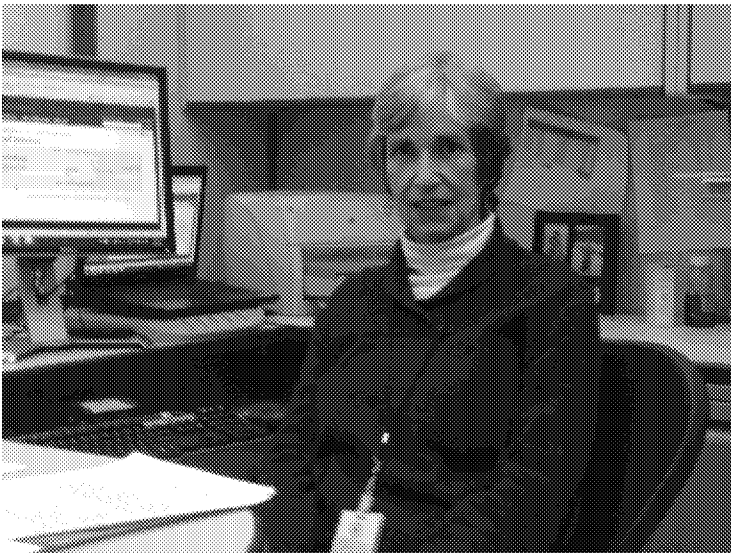
## Presenter Bio



**Dr. H. Christopher Frey** is Distinguished University Professor of Environmental Engineering in the Department of Civil, Construction, and Environmental Engineering at NC State. His research activities are in: measurement and modeling of real-world fuel use and emissions of onroad and nonroad vehicles; measurement and modeling of human exposure to air pollutants; environmental risk analysis, quantification of sensitivity, uncertainty, and variability in systems models; and modeling and evaluation of energy and environmental

control systems. He is Chair of the EPA Clean Air Scientific Advisory Committee and has previously served on CASAC review panels for all six criteria pollutants regulated under the National Ambient Air Quality Standards. He is past president and a fellow of the Society for Risk Analysis and a fellow of the Air & Waste Management Association. Dr. Frey has a B.S. Mechanical Engineering from the University of Virginia, and from Carnegie Mellon University he has a Master of Engineering in Mechanical Engineering and PhD in Engineering and Public Policy.

## Moderator Bio



**Dr. Holly Stallworth** is an economist in EPA's Science Advisory Board Staff Office. She has been at EPA since 1980 and Designated Federal Officer (DFO) for the Clean Air Scientific Advisory Committee (CASAC) since 2009. In that capacity, she has managed the chartered CASAC as well as some of its panels, including panels on ozone, particulate matter and oxides of nitrogen and sulfur. As DFO, she recruits

scientists who serve on the chartered CASAC as well as CASAC panels. She also assists the Chair in drafting and editing CASAC reports so that they clearly reflect CASAC's consensus response to EPA's charge questions. Finally, she is responsible for the day-to-day administration of CASAC, ensuring that the requirements of the Federal Advisory Committee Act (FACA) are met through open meetings announced in the Federal Register, posting minutes on the CASAC website ([www.epa.gov/casac](http://www.epa.gov/casac)) and providing opportunities for public comment at CASAC meetings.

# **Behind the Invisible Curtain at the U.S. EPA Clean Air Scientific Advisory Committee (CASAC): What CASAC Does and How**

**H. Christopher Frey**

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**Prepared for:  
Air & Waste Management Association**

**January 8, 2014**



# DISCLAIMER

- These are my **personal views**
- They do not represent any official position of U.S. Environmental Protection Agency (EPA) or the EPA Clean Air Scientific Advisory Committee (CASAC)

# Overview

- Statutory Mandate: NAAQS, CASAC
- CASAC's Charter
- NAAQS Review Process
- CASAC Meetings
- Appointment of Members: CASAC, Panels
- FACA and CASAC
- Scope of CASAC
- CASAC, NAAQS and the Courts
- EPA Inspector General's Report
- Summary of Recent CASAC Activities
- Broad Science-based Issues

# CASAC

- Clean Air Scientific Advisory Committee (CASAC)
- Independent advice to the EPA Administrator on technical bases for National Ambient Air Quality Standards (NAAQS).
- Established in 1977 under the Clean Air Act (CAA) Amendments of 1977

## Statutory Mandate for National Ambient Air Quality Standards

- Section 108 of Clean Air Act
  - Identify and list certain air pollutants
  - Issue **air quality criteria** for those pollutants.
  - In Administrator's "judgment, cause or contribute to air pollution which may reasonably be anticipated to **endanger public health or welfare**;"
  - "the presence of which in the ambient air results from **numerous or diverse mobile or stationary sources**;"
  - "**accurately reflect the latest scientific knowledge**"

## National Ambient Air Quality Standards: “Primary Standard”

- “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an **adequate margin of safety**, are **requisite to protect the public health.**”
  - Intended to address uncertainties
  - Reasonable degree of protection
  - Does not require zero risk
  - Interpretation has been reviewed in numerous court cases

## **“Adequate Margin of Safety”**

Factors considered by EPA:

- nature and severity of the health effects
- size of sensitive population(s) at risk, and
- the kind and degree of uncertainties

## National Ambient Air Quality Standards: “Secondary Standard”

- “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is **requisite to protect the public welfare** from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”
- “Welfare” generally refers to endpoints other than human health. Examples
  - Ecological impact
  - Reduction in visibility
  - Damage to materials

## Cost and Standard Setting

- In setting a NAAQS, EPA may not consider costs of implementing the standards (Whitman v. American Trucking Associations, 2001).
- “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.” (American Petroleum Institute v. Costle)



## Key Elements of a NAAQS

- Indicator (Pollutant)
- Level
- Averaging Time
- Form

# Current National Ambient Air Quality Standards (NAAQS) as of October 2013

Pollutant	Primary/ Secondary	Averaging Time	Level	Form
CO	primary	8-hour	9 ppm	Not to be exceeded more than once per year
		1-hour	35 ppm	
Lead	primary and secondary	Rolling 3 month average	0.15 µg/m <sup>3</sup>	Not to be exceeded
NO <sub>2</sub>	primary and secondary	Annual	53 ppb	Annual mean
	primary	1-hour	100 ppb	98 <sup>th</sup> percentile of 1-hour daily maximum concentrations, averaged over 3 years
O <sub>3</sub>	primary and secondary	8-hour	0.075 ppm	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
PM <sub>2.5</sub>	primary	Annual	12.0 µg/m <sup>3</sup>	annual mean, averaged over 3 years
	secondary		15.0 µg/m <sup>3</sup>	
	primary and secondary	24-hour	35 µg/m <sup>3</sup>	98 <sup>th</sup> percentile, averaged over 3 years
PM <sub>10</sub>	primary and secondary	24-hour	150 µg/m <sup>3</sup>	Not to be exceeded more than once per year on average over 3 years
SO <sub>2</sub>	primary	1-hour	75 ppb	99 <sup>th</sup> percentile of 1-hour daily maximum concentrations, averaged over 3 years
	secondary	3-hour	0.5 ppm	Not to be exceeded more than once per year

Primary (health-based) and secondary (welfare-based) standards. Units of measure are parts per million (ppm), parts per billion (ppb) or micrograms per cubic meter of air (µg/m<sup>3</sup>). For more information about the standards, visit <http://www.epa.gov/ttn/naaqs/>.

## Statutory Mandate for Five Year Review Cycle

- Section 109(d)(1) requires that “not later than December 31, 1980, and at **5-year intervals** thereafter, the Administrator shall complete a **thorough review** of the criteria published under section 108 and the national ambient air quality standards . . . and **shall make such revisions in such criteria and standards** and **promulgate such new standards** as may be appropriate . . . .”

## Statutory Mandate for CASAC

- Section 109(d)(2) requires that an independent scientific review committee
  - “shall complete a **review of the criteria** . . .
  - “and the national primary and secondary ambient air quality standards . . .
  - “and shall **recommend to the Administrator** any **new** . . . standards and **revisions** of existing criteria and standards as may be appropriate . . . .”

## CASAC's Charter

- a) (...) recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate
- b) Advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards
- c) Describe the research efforts necessary to provide the required information

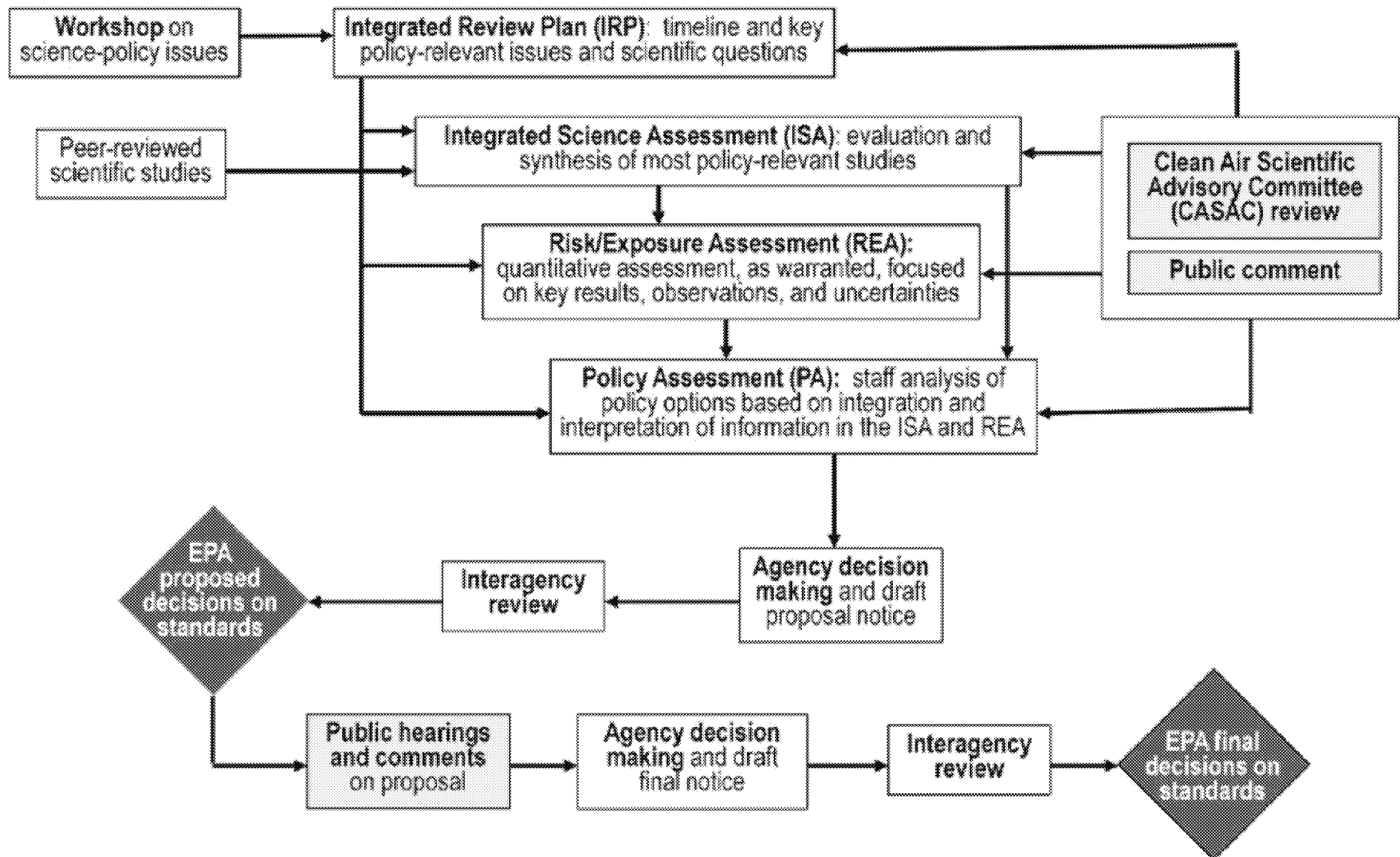
## CASAC's Charter

- d) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity
- e) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards

NOTE: (e) is not part of the standards review process and overlaps with the scope of CAAAC and ACCACA

# NAAQS Review Process

(since 2006, with revisions)

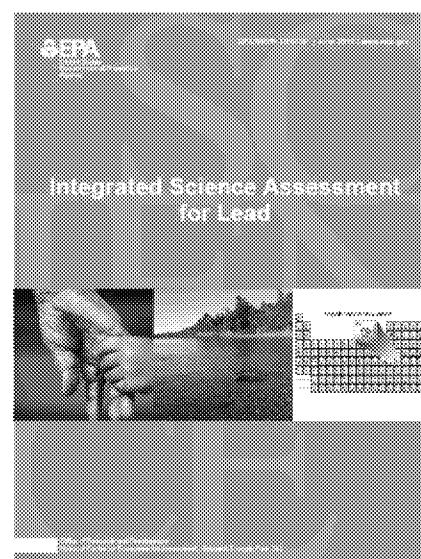
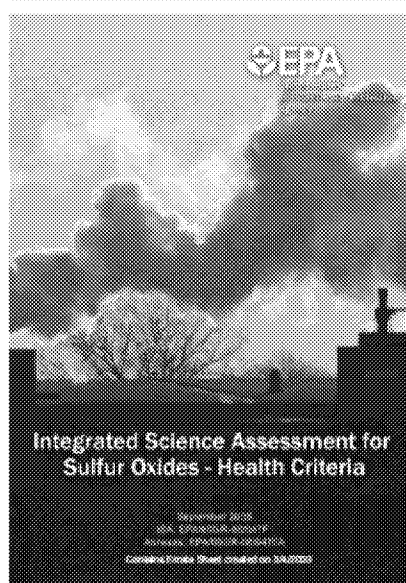
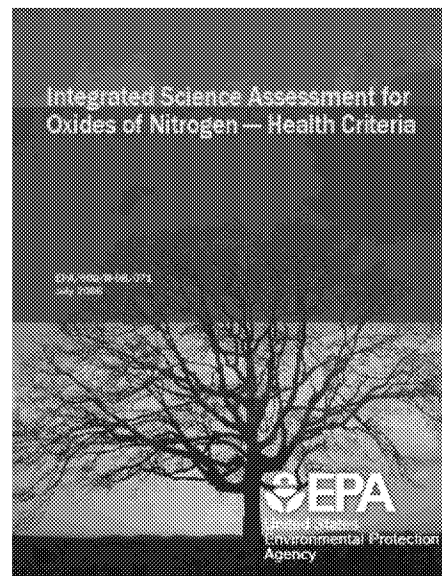
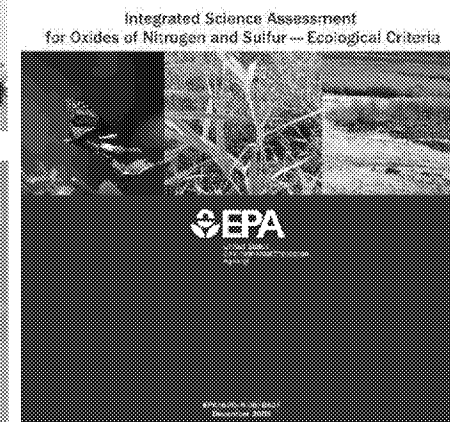
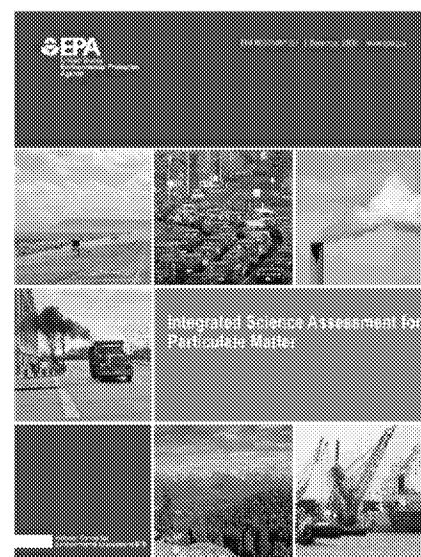
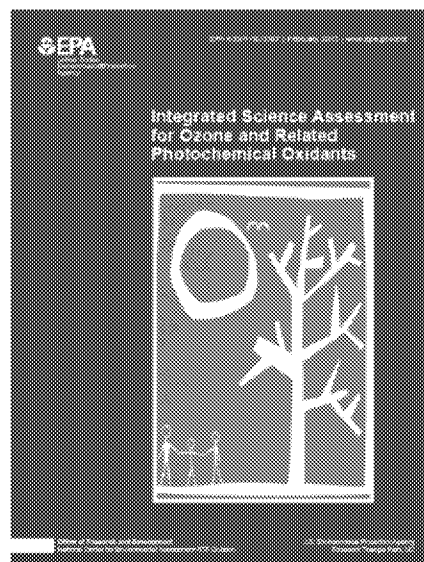
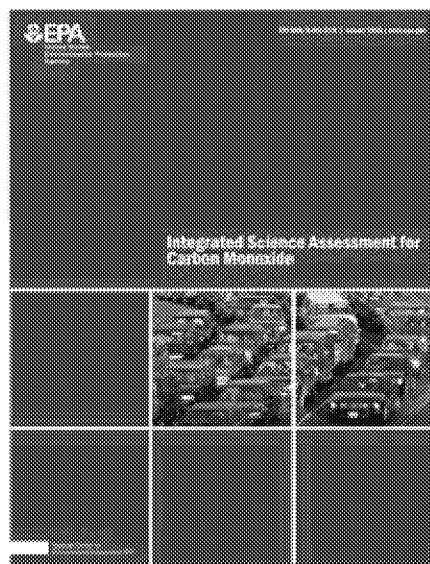


## NAAQS Review Process

- **IRP** Integrated Review Plan
- **ISA** Integrated Science Assessment
- **REA** Risk and Exposure Assessment
- **PA** Policy Assessment



# Integrated Science Assessments



## NAAQS Review Process

- Timing (example):
  - From IRP to last draft of PA is typically 3 years
  - Consultation (now review): IRP
  - Meeting 1: 1<sup>st</sup> draft ISA
  - Meeting 2: 2<sup>nd</sup> draft ISA, 1<sup>st</sup> draft REA
  - Meeting 3: 3<sup>rd</sup> draft ISA (?), 2<sup>nd</sup> draft REA, 1<sup>st</sup> draft PA
  - Meeting 4: 2<sup>nd</sup> draft PA

Each meeting is typically 1.5 to 2 days, held in Research Triangle Park, NC area

## Preparing for a CASAC Meeting

- EPA staff (NCEA, OAQPS) prepare draft document(s) for review (ISA, REA, PA)
- EPA staff prepare draft charge questions
- Iterate with panel chair on draft charge questions
- Panel chair assigns charge questions to panel members based on topic and expertise
- Typically aim for 60 days of review time before panel meeting
- Panelists prepare individual “pre-meeting” written comments

## At a CASAC Meeting

- EPA staff (NCEA, OAQPS) give a presentation on the draft document(s)
- Opportunity for clarifying questions from panel members
- Public comment
- Opportunity for clarifying questions from panel members
- Panelists must present and deliberate their comments in the public session
- “Lead discussant” for each charge question drafts consensus response
- Seek agreement on key points to be included in letter to Administrator and responses to charge questions

## After a CASAC Meeting

- Chair prepares draft letter with attached charge questions and responses
- Panel reviews and finalize in a post-meeting teleconference (public notice, open to the public, opportunity for public comment)
- Seek panel consensus and concordance with draft letter
- Panelists can submit final 'post-meeting' written comments
- Quality review by chartered CASAC
- Letter sent to Administrator

# Appointment of CASAC Members

- Annual nomination process
- Published in Federal Register
- Opportunity for public comment
- Appointed by EPA Administrator
- Members of chartered CASAC serve a 3 year term
- Can be reappointed for a 2<sup>nd</sup> 3 year term
- Chair is appointed for a 2 year term. Can be renewed for a 2<sup>nd</sup> 2 year term

## Chartered CASAC Members

- Must include
  - Seven members
  - A physician
  - A member of the National Academy of Sciences (or equivalent – e.g., IOM)
  - One person representing state air control agencies

# CASAC Review Panels

- The 7 member statutory CASAC is augmented for specific review activities:
  - Ozone Review Panel
  - Oxides of Nitrogen Review Panel
  - Oxides of Sulfur Review Panel
  - Carbon Monoxide Review Panel
  - Lead Review Panel
  - Particulate Matter Review Panel
  - Secondary SO<sub>x</sub> and NO<sub>x</sub> Review Panel
  - Air quality monitoring and modeling review panel



# CASAC Review Panels

- Opportunity for the public to nominate candidates for the panels
- Balance of scientific and technical expertise
- Sufficient scope of scientific and technical expertise to review and evaluate the ISA, REA, and PA
- Panel members are appointed by the SAB director
- Chartered CASAC members serve on each panel
- A member of Chartered CASAC chairs each panel
- Chartered CASAC augmented by typically ~15 experts per panel

## **Chartered CASAC and Advise to Administrator**

- All advice from CASAC to the Administrator is from the Chartered CASAC
- Panels draft CASAC letter reports and appendices (e.g., responses to charge questions)
- Typically seek panel consensus
- “Quality Review” by chartered CASAC

## Panel Composition

- Technical expertise (example of Lead review panel):
  - Atmospheric sciences, air quality
  - Transport and fate
  - Exposure assessment
  - Toxicology
  - Biokinetic modeling
  - Epidemiology
  - Risk assessment
  - Biostatistics
  - Ecology

# CASAC and Panel Members

- Appointed as “Special Government Employees” (SGE)
  - Limited service to the Government
  - Provide outside expertise or perspectives
  - Advisory or committee members
  - Subject to ethics rules (examples)
    - » Financial disclosure and filing
    - » Conflict of Interest
    - » Prohibition of “representation”
    - » May not further private interests
    - » Gifts, bribery
    - » Hatch Act
    - » Fundraising
    - » Expert testimony

## **CASAC and FACA**

- FACA: Federal Advisory Committee Act
- CASAC operates as a FACA committee
- Public notice of meetings
- Meetings held in public
- Opportunity for public comment
- Deliberations are in public
- CASAC issues written letter reports with attachments to the Administrator

## Public Comment

- CASAC deals with scientific issues related to advising the Administrator - e.g., indicator, level, averaging time, and form of an existing NAAQS, revised NAAQS, possible new NAAQS
- Public comments based on peer reviewed science can be very useful
- Opportunity for public comment is provided at every CASAC meeting
- Opportunity for public nomination of candidates for CASAC and CASAC Panels

# Chartered CASAC: Current Members



Members of the Clean Air x

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## Members of the Clean Air Scientific Advisory Committee

<a href="#">Frey, H. Christopher</a>	<b>Chair</b> North Carolina State University	Raleigh	NC
<a href="#">Allen, George A.</a>	Northeast States for Coordinated Air Use Management (NESCAUM)	Boston	MA
<a href="#">Diez-Roux, Ana</a>	University of Michigan	Ann Arbor	MI
<a href="#">Harkema, Jack</a>	Michigan State University	East Lansing	MI
<a href="#">Suh, Helen</a>	Northeastern University	Boston	MA
<a href="#">Weathers, Kathleen</a>	Cary Institute of Ecosystem Studies	Millbrook	NY
<a href="#">Wyzga, Ronald</a>	Electric Power Research Institute	Palo Alto	CA

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# CASAC Website

EPA Clean Air Scientific A x

yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC

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**Science Advisory Board**  
**Advisory Council on Clean Air Compliance Analysis**

The **Clean Air Scientific Advisory Committee (CASAC)** provides independent advice to the EPA Administrator on the technical bases for EPA's national ambient air quality standards. Established in 1977 under the Clean Air Act (CAA) Amendments of 1977 (see 42 U.S.C. § 7409(d)(2)), CASAC also addresses research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality. The Chair of the CASAC also serves as a member of the chartered Science Advisory Board.

This website provides information on:

- [the seven members of CASAC](#), including the [annual process for nominating and providing comment on candidate experts](#) to serve CASAC,
- CASAC [advisory activities](#) and [reports](#) (both [activities](#) and [reports](#) can be viewed by CASAC topic),
- [how you can participate in the science advisory process](#), including the use of EPA's [Web-based process](#) for public nomination of experts,
- how to contact the CASAC's Designated Federal Officer to obtain additional information about the CASAC, and
- [CASAC input on EPA's revised NAAQS review process](#)

Our [recent additions](#) page provides information on recent draft reports, Federal Register notices, upcoming meetings, recently announced advisory activities, and recently finalized reports.

**Designated Federal Officer:** Holly Stallworth  
 202-564-2073  
[stallworth.holly@epa.gov](mailto:stallworth.holly@epa.gov)

**Related Scientific Advisory Committees**

Science Advisory Board (SAB)  
 Advisory Council on Clean Air Compliance Analysis (Council)

**Recent Happenings**

- Public Input
  - Upcoming meetings
- Advisory reports
- Get CASAC Recent Happenings delivered to your feed reader | [More about RSS news feeds \(USA.gov\)](#)



# CASAC Current Panels: Ozone

Ozone Review Panel | EPA x

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- Advisory Council on Clean Air Compliance Analysis

## Ozone Review Panel

The CASAC Ozone Review Panel is charged with providing advice on the scientific and technical aspects of the policy-relevant science and the National Ambient Air Quality Standards (NAAQS) for ozone.

**Members:**

<u>Frey, H. Christopher</u>	<b>Chair</b> North Carolina State University	Raleigh	NC
<u>Allen, George A.</u>	Northeast States for Coordinated Air Use Management (NESCAUM)	Boston	MA
<u>Avol, Ed</u>	University of Southern California	Los Angeles	CA
<u>Bell, Michelle</u>	Yale University	New Haven	CT
<u>Brain, Joseph D.</u>	Harvard University	Boston	MA
<u>Chock, David</u>	Independent Consultant	Bloomfield Hills	MI
<u>Diez-Roux, Ana</u>	University of Michigan	Ann Arbor	MI
<u>Foster, William Michael</u>	Duke University Medical Center	Durham	NC
<u>Grantz, David A.</u>	University of California at Riverside, Kearney Agricultural Center	Parlier	CA
<u>Harkema, Jack</u>	Michigan State University	East Lansing	MI
<u>Jacob, Daniel</u>	Harvard University	Cambridge	MA
<u>Kleeberger, Steven</u>	National Institutes of Health	Research Triangle Park	NC
<u>Miller, Frederick J.</u>	Independent Consultant	Cary	NC
<u>Neufeld, Howard</u>	Appalachian State University	Boone	NC
<u>Russell, Armistead (Ted)</u>	Georgia Institute of Technology	Atlanta	GA
<u>Samet, Jonathan M.</u>	University of Southern California	Los Angeles	CA
<u>Suh, Helen</u>	Northeastern University	Boston	MA
<u>Ullman, James</u>	Pennsylvania State University	University Park	PA
<u>Vedal, Sveng</u>	University of Washington	Seattle	WA
<u>Weathers, Kathleen</u>	Cary Institute of Ecosystem Studies	Millbrook	NY
<u>Woodbury, Peter</u>	Cornell University	Ithaca	NY
<u>Wyzga, Ronald</u>	Electric Power Research Institute	Palo Alto	CA

# CASAC Current Panels: Oxides of Nitrogen

CASAC Oxides of Nitrogen

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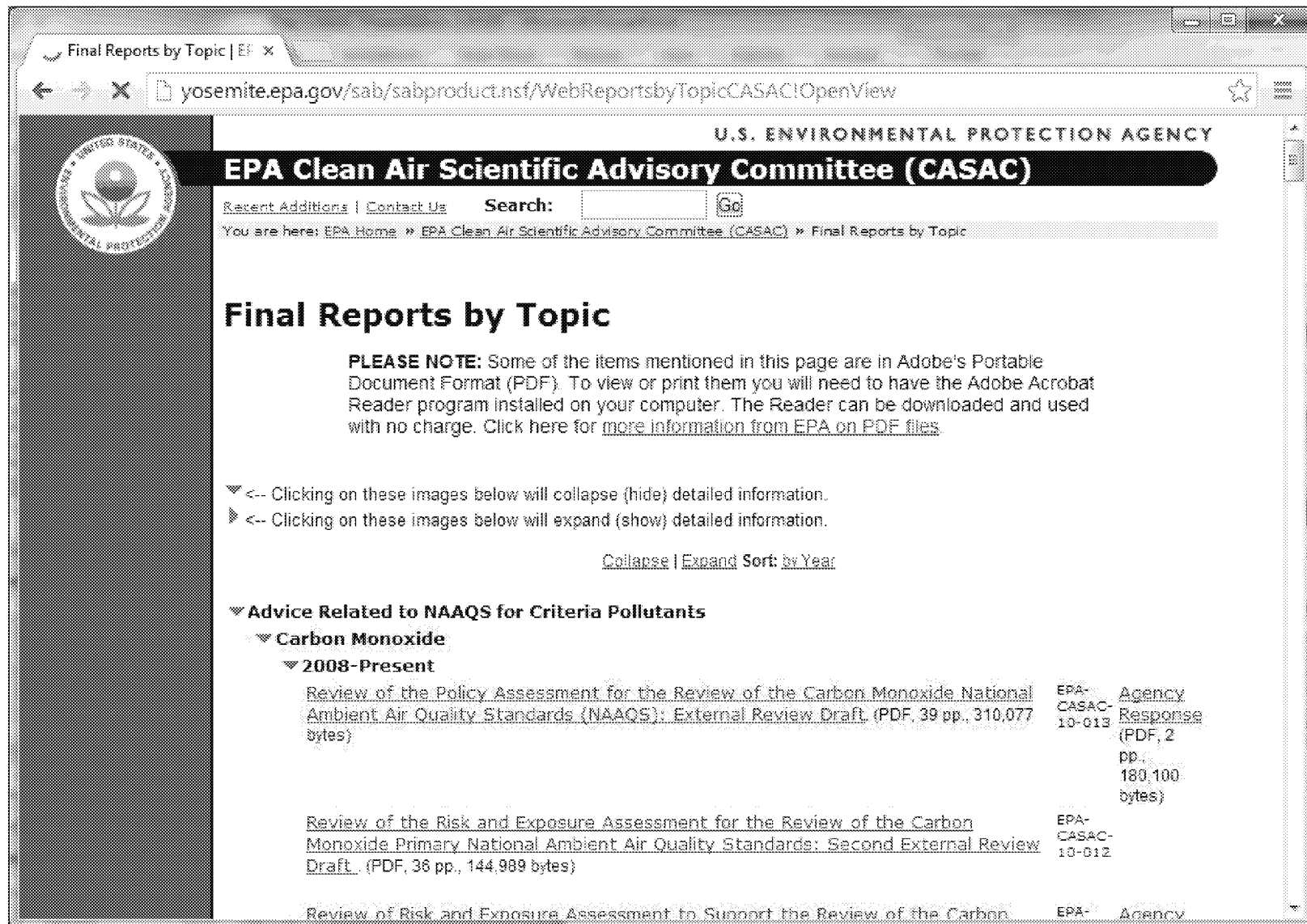
**CASAC Oxides of Nitrogen Primary NAAQS Review Panel (2013-2016)**

**Designated Federal Officer:** Aaron Yeow  
 202-564-2050  
[yeow.aaron@epa.gov](mailto:yeow.aaron@epa.gov)

**Members:**

<a href="#">Frey, H. Christopher</a>	<b>Chair</b> North Carolina State University	Raleigh	NC
<a href="#">Allen, George A.</a>	Northeast States for Coordinated Air Use Management (NESCAUM)	Boston	MA
<a href="#">Campen, Matthew</a>	University of New Mexico	Albuquerque	NM
<a href="#">Cohen, Ronald</a>	University of California, Berkeley	Berkeley	CA
<a href="#">Dockery, Douglas</a>	Harvard University	Boston	MA
<a href="#">Fine, Philip</a>	South Coast Air Quality Management District	Diamond Bar	CA
<a href="#">Georgopoulos, Panos</a>	UMDNJ-Robert Wood Johnson Medical School	Piscataway	NJ
<a href="#">Harkema, Jack</a>	Michigan State University	East Lansing	MI
<a href="#">Jerrett, Michael</a>	University of California, Berkeley	Berkeley	CA
<a href="#">Kaufman, Joel</a>	University of Washington	Seattle	WA
<a href="#">Kinney, Patrick</a>	Columbia University	New York	NY
<a href="#">Kleinman, Michael T.</a>	University of California, Irvine	Irvine	CA
<a href="#">Larson, Timothy V.</a>	University of Washington	Seattle	WA
<a href="#">Samat, Jeremy</a>	Emory University	Atlanta	GA
<a href="#">Schlesinger, Richard</a>	Pace University	New York	NY
<a href="#">Sheppard, Elizabeth A. (Lianne)</a>	University of Washington	Seattle	WA
<a href="#">Suh, Helen</a>	Northeastern University	Boston	MA
<a href="#">Wyzga, Ronald</a>	Electric Power Research Institute	Palo Alto	CA
<a href="#">Zhang, Junfeng (Jim)</a>	Duke University	Durham	NC

# CASAC Reports are Publicly Available



The screenshot shows a web browser window displaying the EPA Clean Air Scientific Advisory Committee (CASAC) website. The browser's address bar shows the URL: `yosemite.epa.gov/sab/sabproduct.nsf/WebReportsbyTopicCASAC!OpenView`. The website header includes the EPA logo and the text "U.S. ENVIRONMENTAL PROTECTION AGENCY" and "EPA Clean Air Scientific Advisory Committee (CASAC)". Below the header, there is a search bar and a breadcrumb trail: "You are here: EPA Home » EPA Clean Air Scientific Advisory Committee (CASAC) » Final Reports by Topic".

## Final Reports by Topic

**PLEASE NOTE:** Some of the items mentioned in this page are in Adobe's Portable Document Format (PDF). To view or print them you will need to have the Adobe Acrobat Reader program installed on your computer. The Reader can be downloaded and used with no charge. Click here for [more information from EPA on PDF files](#).

▼ <-- Clicking on these images below will collapse (hide) detailed information.  
 ▶ <-- Clicking on these images below will expand (show) detailed information.

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### ▼ Advice Related to NAAQS for Criteria Pollutants

#### ▼ Carbon Monoxide

##### ▼ 2008-Present

<a href="#">Review of the Policy Assessment for the Review of the Carbon Monoxide National Ambient Air Quality Standards (NAAQS): External Review Draft</a> (PDF, 39 pp., 310,077 bytes)	EPA-CASAC-10-013	Agency Response (PDF, 2 pp., 180,100 bytes)
<a href="#">Review of the Risk and Exposure Assessment for the Review of the Carbon Monoxide Primary National Ambient Air Quality Standards: Second External Review Draft</a> (PDF, 36 pp., 144,989 bytes)	EPA-CASAC-10-012	
<a href="#">Review of Risk and Exposure Assessment to Support the Review of the Carbon</a>	EPA-	Agency

# Nominating Experts to Advisory Panels and Ad Hoc Committees

The screenshot shows a web browser window with the URL `yosemite.epa.gov/sab/sabproduct.nsf/Web/participatepanelformation?OpenDocument`. The page header includes the EPA logo and the text "U.S. ENVIRONMENTAL PROTECTION AGENCY". The main heading is "EPA Science Advisory Board Staff". Below this is a search bar and a breadcrumb trail: "You are here: EPA Home » EPA Science Advisory Board Staff » Nominate Experts to Advisory Panels and Ad Hoc Committees".

The left sidebar contains a menu with the following items: "EPA SAB Staff Home", "About Us", "Publications", "Public Involvement in Advisory Activities", "Nomination of Experts", "Ethics Requirements for Advisors", "Science Advisory Board", "Clean Air Scientific Advisory Committee", and "Advisory Council on Clean Air Compliance Analysis".

The main content area has the heading "Nominate Experts to Advisory Panels and Ad Hoc Committees". Below this is a sub-heading "Nomination to Advisory Panels and Ad Hoc Committees". The text states: "The public may nominate experts to serve on panels and *ad hoc* committees being formed to address specific advisory topics. The SAB Staff Office announces the formation of such panels and committees and solicits public nominations in the Federal Register for the [SAB](#), [CASAC](#), and the [Council](#)."

It then says: "If you wish to nominate yourself or another expert, please follow the instructions below:"

1. If you wish to nominate an expert currently or recently serving on the SAB, CASAC, Council or one of their committees or panels, [review this reference list](#) (which opens as a pop-up) and complete and submit the [Nomination to Panel or Committee Being Formed](#).
2. If you wish to nominate an expert who is NOT currently or has NOT recently served on the SAB, CASAC, Council or one of their committees or panels, complete and submit the requested [New Expert Information](#).

After completing the *New Expert Information*, you will be presented with the *Nomination to Panels Being Formed* to complete and submit.

**Opportunities for Input on Candidate Experts for Advisory Panels and Ad Hoc Committees**

The SAB Staff Office invites comments on Lists of Candidates for [SAB](#) or [CASAC](#) panels and committees as Lists become available.

For background information on the SAB process for forming panels, see the SAB Staff Office publication, [Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board, September 2002](#), (PDF, 10 pp., 113 kb, [About PDF Files](#)) and the more detailed description of the formation of advisory panels and ad hoc committees in the [2004 SAB Implementation Plan](#) (PDF, 30 pp., 347 kb, [About PDF Files](#)).

# Scope of CASAC Review and Advice

- Existing NAAQS
- Possible alternatives to existing NAAQS
- New NAAQS?
- Retire an existing NAAQS?

## Beyond the Scope of CASAC

- New Source Performance Standards
- National Emission Standards for Hazardous Air Pollutants
- New Source Review (NSR) (BACT/LAER)
- (etc.)

# Science and Policy

- CASAC differs from some other FACA committees
  - Statutory mandate to advise the Administrator on a specific regulatory-related scope
  - Judgments regarding indicator, level, averaging time, and form of a NAAQS
  - “adequate margin of safety”
  - Court decisions acknowledge role for CASAC in providing scientific and policy-relevant advice.

# CASAC and the Courts

- There have been many court cases related to the NAAQS, some of which that have touched upon CASAC and its role
- The most recent:
  - Mississippi v. EPA (2013)
  - Court of Appeals for the D.C. Circuit affirmed EPA's 2008 NAAQS for ozone of 0.075 ppm
  - “Had CASAC reached a scientific conclusion that adverse health effects were likely to occur at the 0.070 ppm level, EPA's failure to justify its uncertainty regarding the existence of adverse health effects at this level would be unacceptable”



# CASAC and the Courts

- Here's what CASAC said about this in letters to the Administrator:
  - “the current primary 8-hr standard of 0.08 ppm needs to be substantially reduced to be protective of human health, particularly in sensitive subpopulations”
  - “overwhelming scientific evidence”
  - “that the level of the current primary ozone standard should be lowered from 0.08 ppm to no greater than 0.070 ppm.”

# Conflict of Interest?

# MILLOY: Clearing the air on the EPA

## EPA grants to its advisers triggers conflict-of-interest query

COMMENTS (0) SIZE: + / - PRINT | REPRINTS

By Steve Milloy - The Washington Times

Wednesday, March 7, 2012

### Dietzel For U.S. Congress

supportlibertythatwin...  
A Businessman &  
Conservative. Support  
Paul Dietzel Today!



Rep. Joe Barton last week took the first official baby step in exposing the Environmental Protection Agency's corrupt scientific advisory process.

In his opening statement at last week's House Energy and Commerce hearing about the EPA's 2013 budget, Mr. Barton of Texas came as close as any Republican ever has to reading EPA Director Lisa P. Jackson the riot act about the agency's ever-increasing contempt for science, economics, Congress and even the Constitution.

While much of the aforesaid is widely known but typically left unsaid by timid congressional Republicans, Mr. Barton also raised an issue that should shock the conscience of anyone concerned about ethics in government: financial conflict-of-interest among EPA science advisers.

"I want to discuss the EPA's science and research funding and support activities such as the quality assurance supervisory budget and the committees that monitor the EPA's internal activities," Mr. Barton told Ms. Jackson.

"You fund research with grants to people who also serve on your review committees. Is this a conflict of interest? Almost every single member of your Clean Air Science Advisory Committee has been directly or

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EPA grants to

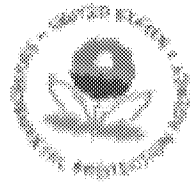
COMMENTS

By Steve Milloy

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF INSPECTOR GENERAL

# EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees

Report No. 13-P-0387

September 11, 2013

## Inspector General Findings

- According to OMB, receipt of a federal grant is not a financial conflict of interest: For grants awarded through a competitive peer review process, agency's potential to influence the scientist's research is limited
- A member's research or grant is a potential concern if a committee or panel plans to address work performed under the grant
- EPA has adequate procedures for identifying financial conflicts of interest

## Inspector General Findings

- SAB Staff Office has adequate procedures for identifying independence and impartiality concerns.
- Documentation can be improved.
- Federal agencies have discretion on setting time limits for committee membership and for procedures for making exceptions.
- EPA has established procedures for “balance” that go beyond minimum requirements
- The OIG also recommended that EPA/NCEA more systematically identify “influential scientific information” for submission to peer review.

# Misconceptions?

- CASAC does not set the NAAQS
  - CASAC advises the Administrator
  - The Administrator has the authority to make decisions regarding a NAAQS
    - » Indicator
    - » Level
    - » averaging time
    - » form

# Key Science Issues (Examples)

- Identification of adverse effects
- Weight of evidence determinations
- Basis for quantifying dose-response
  - Clinical studies
  - Toxicology
  - Epidemiologic studies
  - Other (e.g., surveys)
- Metric of exposure
  - Exposure concentration?
  - Ambient concentration?
- Background levels
- Air quality monitoring methods and data
- Air quality modeling
- Quantification of ecosystem effects
- Quantification of other welfare effects

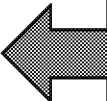
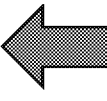
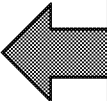
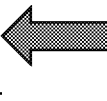
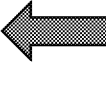


# Framework for Causal Determination Used in ISAs

## Weight of Evidence for Causal Determination

- Causal relationship
- Likely to be a causal relationship
- Suggestive of a causal relationship
- Inadequate to infer a causal relationship
- Not likely to be a causal relationship

# ISAs: Current Framework for Causality Determinations

<b>Causal relationship</b>	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of current levels). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects; or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.	 <div> <p>Rule out chance, confounding, and other biases</p> <p>Consistency, coherence, biological plausibility, high-quality studies</p> </div>
<b>Likely to be a causal relationship</b>	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent; or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.	 <div> <p>Multiple, high-quality studies show effects</p> <p>Uncertainty remains</p> </div>
<b>Suggestive of a causal relationship</b>	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but is limited. For example, (1) at least one high-quality epidemiologic study shows an association with a given health outcome although inconsistencies remain across other studies that are or are not of comparable quality; or (1) a well-conducted toxicological study, such as those conducted in the National Toxicology Program (NTP), shows effects relevant to humans in animal species.	 <div> <p>Evidence is limited</p> <p>Associations found in some high-quality studies but other results inconsistent</p> </div>
<b>Inadequate to infer a causal relationship</b>	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.	 <div> <p>Evidence is of insufficient quantity, quality, consistency</p> </div>
<b>Not likely to be a causal relationship</b>	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestyles, are mutually consistent in not showing an effect at any level of exposure.	 <div> <p>Multiple studies show no effect across exposure concentrations</p> </div>

# Matrix of Causal Determinations from Recent ISAs

		Causality Determination					
Outcome Category	Exposure Period	NO <sub>2</sub> (2008 ISA)	SO <sub>2</sub> (2008 ISA)	PM <sub>2.5</sub> (2009 ISA)	PM <sub>10-2.5</sub> (2009 ISA)	CO (2010 ISA)	O <sub>3</sub> (2013 ISA)
Cardiovascular Morbidity	Short-term	Inadequate	Inadequate	<b>Causal</b>	Suggestive	Likely Causal	Likely Causal
Respiratory Morbidity	Short-term	Likely Causal	<b>Causal</b>	Likely Causal	Suggestive	Suggestive	<b>Causal</b>
Mortality	Short-term	Suggestive	Suggestive	<b>Causal</b>	Suggestive	Suggestive	Likely Causal
Cardiovascular Morbidity	Long-term	Inadequate	Inadequate	<b>Causal</b>	Inadequate	Inadequate	Suggestive
Respiratory Morbidity	Long-term	Suggestive	Inadequate	Likely Causal	Inadequate	Inadequate	Likely Causal
Developmental and Birth Outcomes	Long-term	Inadequate	Inadequate	Suggestive	Inadequate	Suggestive	Suggestive
Mortality	Long-term	Inadequate	Inadequate	<b>Causal</b>	Inadequate	Suggestive of No Causal Relationship	Suggestive

# Causality Determinations for Lead

## Examples:

### Causal Relationship

Children – Cognitive Function Decrements

Externalizing Behavior (Attention, Impulsivity, Hyperactivity)

Adults Hypertension

Coronary Heart Disease

Hematologic Effects

Reproductive Effects

### Likely Causal

Children Internalizing Behaviors

Auditory Function Decrements

Motor Function Decrements

Adults Cognitive Function Decrements

Psychopathological Effects

Immune System Effects

Cancer

# CASAC and the Administrator

- CASAC advises the Administrator
- The Administrator does not always follow the advice.

## Summary of Recent CASAC Advice: Carbon Monoxide

- CASAC expressed a preference for a lower standard but said current evidence also supports retaining the current suite of standards.
- CASAC acknowledged their preference for a lower standard was based on a judgment as to the weight of the epidemiological evidence.
- EPA's final August 2011 decision to retain the primary standard and not set a secondary standard was **compatible** with CASAC's advice.

## **Summary of Recent CASAC Advice: Lead**

- In 2013, CASAC has provided advice that the current standard is adequate
- EPA has not announced a decision regarding the outcome of this review cycle

## Summary of Recent CASAC Advice: Oxides of Nitrogen

- CASAC had recommended the level of the one-hour NO<sub>2</sub> standard should be within the range of 80-100 ppb and not above 100 ppb.
- February 2010: EPA set a 1-hour standard at 100 ppb.
- EPA's decision was **consistent** with CASAC's advice.



## Summary of Recent CASAC Advice: NO<sub>x</sub>-SO<sub>x</sub> Secondary Standard

- In 2011, CASAC had stated that the levels of the current NO<sub>x</sub> and SO<sub>x</sub> secondary NAAQS were not sufficient, nor the forms of those standards appropriate, to protect against adverse depositional effects.
- EPA's April 2012 rule-making that retained the existing NO<sub>2</sub> and SO<sub>2</sub> secondary standards was **NOT consistent** with CASAC's advice.

## Summary of Recent CASAC Advice: Primary Ozone Standard

- For both the 2008 review cycle and a subsequent “reconsideration” of its advice, CASAC had unanimously recommended selection of an 8-hour average ozone NAAQS within the range of 0.060 to 0.070 ppm
- The White House’s decision (Sept. 2011) to retain the 2008 NAAQS standard and withdraw EPA’s proposal to tighten the standard to 0.070 ppm was **NOT consistent** with CASAC advice issued in March 2011 and in prior NAAQS review (2005 – 2008).

## Summary of Recent CASAC Advice: Secondary Ozone Standard

- The same White House decision (Sept. 2011) also postponed any promulgation of the W126-based secondary standard, **contrary** to CASAC's advice.

## Summary of Recent CASAC Advice: Particulate Matter Standard for PM<sub>2.5</sub>

- EPA's Jan. 2013 rule-making that set the primary PM<sub>2.5</sub> annual standard to 12 ug/m<sup>3</sup> while keeping the 24-hour standard of 35 ug/m<sup>3</sup> was **consistent** with CASAC's advice.
- However, EPA decision to retain the secondary annual standard of 15 ug/m<sup>3</sup> **departed** from CASAC advice to introduce a new speciated PM light extinction indicator.
- Similarly, EPA retained the existing secondary 24-hour average of 35 ug/m<sup>3</sup> **contrary** to CASAC advice regarding a 24-hour light extinction-based indicator and level.

## Summary of Recent CASAC Advice: Particulate Matter Standard for PM<sub>10</sub>

- In its Sept. 2010 letter, CASAC recommended that the primary standard for PM<sub>10</sub> should be revised downwards (below 150 ug/m<sup>3</sup>).
- CASAC said that while current evidence is limited, it is sufficient to call into question the level of protection afforded by 150 µg/m<sup>3</sup>.
- The Jan. 2013 decision to retain the current primary and secondary 24-hour average 150 ug/m<sup>3</sup> standard **departed** from CASAC's advice.

## Summary of Recent CASAC Advice: Sulfur Dioxide Primary Standard

- CASAC recommended 50 to 150 ppb.
- EPA's June 2010 decision to establish the 1-hour 75 ppb standard was **consistent** with CASAC advice

# Broad Issues

- Multipollutant air quality management
- Should any existing criteria pollutants be delisted?
- Should other pollutants be designated as criteria pollutants?
- How to deal with potential lack of thresholds and adverse effects near background levels
- How to deal with emerging issues: e.g., climate-air quality interactions

# Accessing Information About CASAC

- All CASAC reports are available via  
[www.epa.gov/casac](http://www.epa.gov/casac)



# QUESTIONS



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# Upcoming Webinar

## Save the Date

### Keeping the Cart out of the Ditch and \$ in Your Pocket: Performing an Air Compliance Audit

Thursday, January 9, 2014

1:00pm-2:30pm (Eastern Time)

#### Presenters:

**Ken Faulkner:** P.E., Principal Environmental Engineer, FC&E Engineering, LLC

**Betty Ruth Fox:** is Counsel with Watkins & Eager

**Chris Wells:** Senior Attorney with the Mississippi Department of Environmental Quality's Environmental Compliance & Enforcement Division.

#### Moderator:

**Dallas Baker:** P.E, Environmental Engineer, Mississippi Department of Environmental Quality and President-Elect in 2014 of A&WMA.



# Upcoming Webinar

## Save the Date

**Towards Sustainable Value Chains**

**Wednesday, January 15, 2014**

**1:00pm-2:30pm (Eastern Time)**

### **Presenters:**

**Jessica Wollmuth:** Supply Chain Sustainability Practice Lead, CH2M HILL

**Jameson Morrell:** Senior Energy and Sustainability Management  
Consultant, CH2M HILL

**Lyra Myers:** Associate Director and Value Creation Agent for Roche's Supplier  
Relationship Center (SRC)



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[rlebovitz@awma.org](mailto:rlebovitz@awma.org) or 412-904-6020**

**Chair: Carol Clinton**

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# Webinar Ideas

**If you have suggestions for other  
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**Robin Lebovitz at  
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